Exhibit B

degussa.

creating essentials

Specifications and test methods for EUDRAGIT® L 100 and EUDRAGIT® S 100

Specification

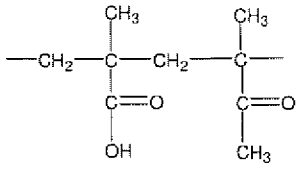
"Methacrylic Acid - Methyl Methacrylate Copolymer (1:1)" Ph. Eur.
"Methacrylic Acid - Methyl Methacrylate Copolymer (1:2)" Ph. Eur.
"Methacrylic Acid Copolymer, Type A and B" USP/NF
"Methacrylic Acid Copolymer L" JPE
"Methacrylic Acid Copolymer S" JPE

1 Commercial form

Solid substances
EUDRAGIT® L 100 and EUDRAGIT® S 100 are described in the monographs quoted above.

2 Chemical structure

EUDRAGIT® L 100 and EUDRAGIT® S 100 are anionic copolymers based on methacrylic acid and methyl methacrylate.



The ratio of the free carboxyl groups to the ester groups is approx. 1:1 in EUDRAGIT® L 100 and approx. 1:2 in EUDRAGIT® S 100.

The average molecular weight is approx. 135,000.

3 Characters

Description

White powders with a faint characteristic odour

Solubility

1 g of EUDRAGIT® L 100 or EUDRAGIT® S 100 dissolves in 7 g methanol, ethanol, in aqueous isopropyl alcohol and acetone (containing approx. 3 % water), as well as in 1 N sodium hydroxide to give clear to slightly cloudy solutions. EUDRAGIT® L 100 and EUDRAGIT® S 100 are practically insoluble in ethyl acetate, methylene chloride, petroleum ether and water.

4 Tests

Test solution

A 12.5 % solution of the dry substance is used for the Test solution: a quantity of EUDRAGIT® L 100 or EUDRAGIT® S 100 corresponding to 12.5 g dry substance is dissolved in a mixture of 84.9 g isopropyl alcohol and 2.6 g water.

Particle size

At least 95 % less than 0.25 mm. The particle size is determined according to Ph. Eur. 2.1.4 or USP <811>.

Film formation

When the Test solution is poured onto a glass plate, a clear film forms upon evaporation of the solvent.

Dry substance / Residue on evaporation

At least 95.0 %. 1 g powder is dried in an oven for 6 hrs at 110 °C, according to Ph. Eur. 2.2.32 method d.

Loss on drying

Max. 5.0 % according to "Dry substance / Residue on evaporation."

Assay

EUDRAGIT® L 100: 46.0 - 50.6 % methacrylic acid units on dry substance (DS)
Acid value: 300 - 330 mg KOH per g DS

EUDRAGIT® S 100: 27.6 - 30.7 % methacrylic acid units on dry substance (DS)
Acid value: 180 - 200 mg KOH per g DS

The assay is performed according to Ph. Eur. 2.2.20 "Potentiometric titration" or USP <541>. Approx. 0.5 g EUDRAGIT® L 100 or EUDRAGIT® S 100 are dissolved in 60 ml isopropyl alcohol and 40 ml water with stirring at approx. 50 °C within 30 to 60 minutes. Sodium hydroxide (NaOH) 0.5 N is used as the titrant. Under the same conditions, a blank value is determined. 1 ml 0.5 N NaOH corresponds to 43.045 mg methacrylic acid units.

$$\text{Methacrylic acid units (\%) on DS} = \frac{\text{ml 0.5 N NaOH} \cdot 430.45}{\text{sample weight (g)} \cdot \text{DS (\%)}}$$

The acid value (AV) states how many mg KOH are required to neutralise the acid groups contained in 1 g dry substance.

AV (mg KOH / g DS) = methacrylic acid units (%) · 6.517

Viscosity / Apparent viscosity

EUDRAGIT® L 100 and EUDRAGIT® S 100: 50 - 200 mPa · s.
The viscosity of the Test solution is determined by means of a Brookfield viscometer (spindle 1 / 30 rpm / 20 °C).

EUDRAGIT® L 100: 10 - 24 mm^2/s
EUDRAGIT® S 100: 22 - 52 mm^2/s
according to JPE.

Refractive index

n_D^{20}: 1.390 - 1.395. The refractive index of the Test solution is determined according to Ph. Eur. 2.2.6.

Relative density

d_{20}^{20}: 0.831 - 0.852. The relative density of the Test solution is determined according to Ph. Eur. 2.2.5.

5 Purity

Sulphated ash / Residue on ignition

Max. 0.1 % according to Ph. Eur. 2.4.14 or USP <281>. 1 g EUDRAGIT® L 100 or EUDRAGIT® S 100 is used for the test.

Heavy metals

Max. 20 ppm according to Ph. Eur. 2.4.8 method C or USP <231> method II. 1 g EUDRAGIT® L 100 or EUDRAGIT® S 100 is used for the test.

Arsenic

Max. 2 ppm according JP Method 3, Apparatus B. 1.0 g EUDRAGIT® L 100 or EUDRAGIT® S 100 is used for the test.

Monomers

Max. 500 ppm, according to the Ph. Eur. or USP/NF monographs.

Microbial count

Max. 1,000 CFU / g; Salmonella not detectable in 10 g, E. coli, S. aureus, Ps. aeruginosa not detectable in 1 g. The test is performed according to Ph. Eur. 2.6.12 and 2.6.13.

6 Identity testing

First identification

The material must comply with the tests for "Assay" and "Viscosity / Apparent viscosity."

Second identification

IR spectroscopy on a dry film approx. 15 µm thick. To obtain the film, a few drops of the Test solution are placed on a crystal disc (KBr, NaCl) and dried in vacuo for about 2 hours at 70 °C.

The figures on page 4 show the characteristic bands of the C=O vibrations of the carboxylic acid groups at 1,705 cm^{-1} and of the esterified carboxyl groups at 1,730 cm^{-1}, as well as further ester vibrations at 1,150 - 1,160, 1,190 - 1,195 and 1,250 - 1,275 cm^{-1}. The wide absorption range of the associated OH groups between 2,500 and 3,500 cm^{-1} is superimposed by CH_x vibrations at 2,900 - 3,000 cm^{-1}. Further CH_x vibrations can be discerned at 1,385 - 1,390, 1,450 and 1,485 cm^{-1}.

EUDRAGIT® L 100 and EUDRAGIT® S 100 differ in intensity in several bands. Thus, the more intensive C=O band of the carboxylic acid groups at 1,705 cm^{-1} shows that EUDRAGIT® L 100 has a higher methacrylic acid content.

7 Detection in dosage forms

The dosage forms are extracted using the solvents listed under "Solubility," if necessary after crushing. Insoluble substances are isolated by filtration or centrifugation. The clear filtrate is boiled down and the residue identified by IR spectroscopy.

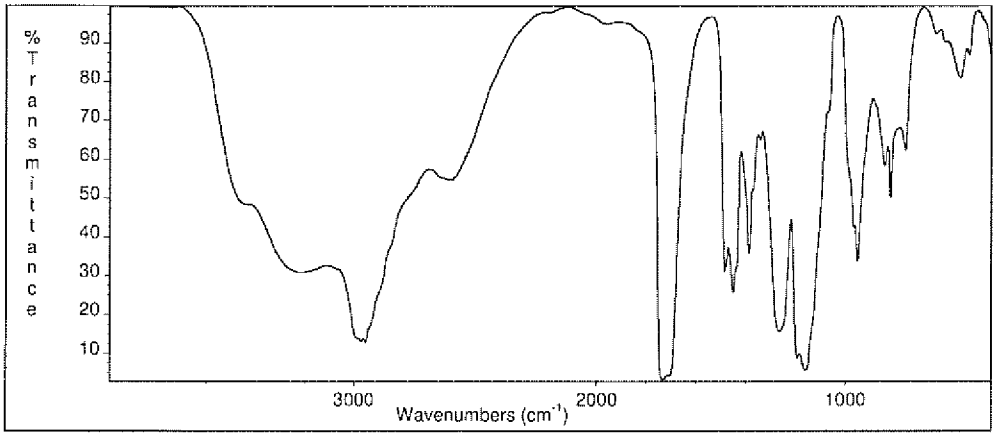
8 Storage

Protect from warm temperatures (USP, General Notices).
Protect against moisture.

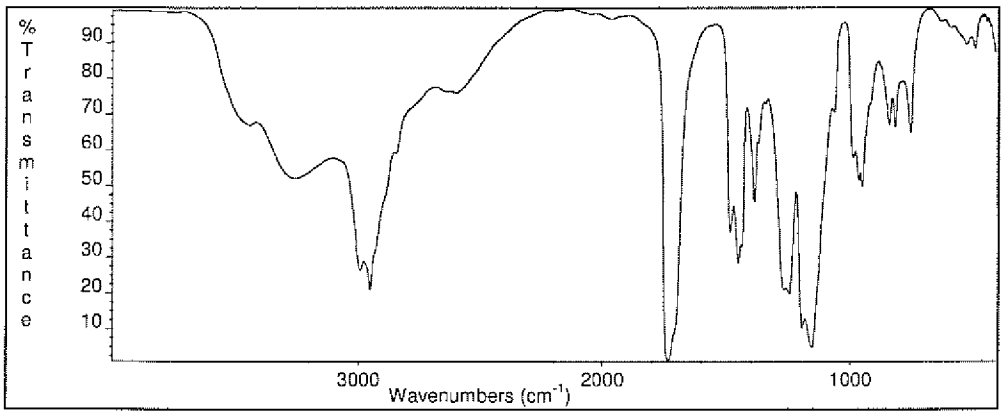
9 Stability

Minimum stability dates are given on the product labels and batch-related Certificates of Analysis. Storage Stability data are available upon request.

EUDRAGIT® L 100



EUDRAGIT® S 100



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